K111010
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510(k) Summary

SpiderFX® Embolic Protection Device

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 C.F.R § 807.92.

1. Submitter Information

Applicant	ev3 Inc. 3033 Campus Drive Plymouth, MN 55441-2651 Tel: 763-398-7000 Fax: 763-591-3248
Contact Person	Brenda Johnson Principal Regulatory Affairs Specialist
Date Prepared	October 26, 2011

2. Subject Device

Device Trade Name	SpiderFX® Embolic Protection Device
Device Common Name	Embolic Protection Device
Classification Name	Temporary Carotid Catheter for Embolic Capture 21 CFR 870.1250, Product Code NTE
Classification Panel	Cardiovascular

3. Predicate Devices

Device Trade Name	SpiderFX® Embolic Protection Device; SpideRX® Embolic Protection Device Angioslide eXtra™ PTA Balloon Catheter with Embolic Capture Feature
510(k) Number	K063204; K052659; K090364
510(k) Clearance Date	November 14, 2006; February 17, 2006; March 23, 2010

4. Device Description

The SpiderFX® Embolic Protection Device is a percutaneously delivered distal embolic protection system that can be delivered over any 0.014" or 0.018" guidewire. The SpiderFX Embolic Protection Device contains a Capture Wire composed of a nitinol mesh filter mounted on a 190 cm or a convertible 320/190 cm PTFE-coated 0.014" stainless steel guidewire and a dual-ended SpiderFX Catheter for delivery and recovery. The SpiderFX® Embolic Protection Device uses the following materials: pebax, grilamid, platinum/iridium, nitinol, stainless steel, PTFE coating, gold tungsten, and hydrophilic coating.

5. Indications for Use

The SpiderFX® Embolic Protection Device is indicated for use as a guidewire and embolic protection system to contain and remove embolic material in conjunction with the TurboHawk, either during standalone procedures or together with PTA and/or stenting, in the treatment of severely calcified lesions in arteries of the lower extremities.

6. Comparison of Technological Characteristics

The SpiderFX® Embolic Protection Device is the identical device as the currently marketed SpiderFX Embolic Protection Device (K063204). The SpiderFX Embolic Protection Device for peripheral use and the predicate SpiderFX Embolic Protection Device for carotid use share the following technological characteristics:

- Intended use
- Fundamental scientific technology and operating principle
- Design & Dimensions
- Materials
- Manufacturing site and methods
- Sterilization site, method, parameters, and sterility assurance level
- Packaging
- Shelf Life

Additionally, the Indications for Use, labeling, and Instructions For Use are similar between the proposed and marketed devices. The differences include a revised sizing matrix for use during interventions in lower extremity vessels, allowing use of the SpiderFX Device with atherectomy interventional devices, and allowing use of commercially available catheters, that are minimally 0.035" guide wire compatible, for delivery and/or recovery of the SpiderFX Capture Wire. Bench and animal testing was performed to demonstrate the proposed use of the device met pre-determined acceptance criteria.

7. Biocompatibility Testing

Device materials in the proposed SpiderFX® Embolic Protection Device are identical to the materials in the commercially available SpiderFX® and SpideRX® Embolic Protection Devices. Biocompatibility testing was leveraged from the predicate SpiderFX® and SpideRX® Embolic Protection Device submissions and included cytotoxicity, sensitization, intracutaneous injection, systemic injection, hemolysis, pyrogen, complement activation, and thrombogenicity. The SpideRX Catheter and Capture Wire from the predicate SpideRX Device (K052659) meet the requirements for biocompatibility testing outlined in ISO 10993-1 Part 1: 2003 "Biological Evaluation of Medical Devices".

8. Performance Testing Summary

To demonstrate substantial equivalence of the subject SpiderFX® Embolic Protection Device to the predicate device, the technological characteristics and performance criteria were evaluated. Using FDA Guidance Documents on non-clinical testing of medical devices and internal Risk Analysis procedures, the following tests were performed:

- Stent Compatibility
- Filter Efficiency
- Radial Outward Force
- Simulated Use
- Deployment/Retrieval Forces
- *In Vivo* Animal Studies

The following testing was leveraged from the predicate SpiderFX® and SpideRX® Embolic Protection Device submissions. Test results met the specified acceptance criteria and were included in K063204 or K052659:

- Embolic Capture Efficiency and Retrieval Ability
- Simulated Use
- Deployment/Retrieval Forces
- Filter Capacity
- Resistance to Filter Rupture During Removal of a Fully Loaded Filter
- Flow Characteristics
- Tip Flexibility
- Tensile Strength
- Torque Strength
- Torque Response
- Kink Resistance
- Dimensional Verification
- Package Integrity
- Sterilization
- Shelf Life

The results from these tests demonstrate that the technological characteristics and performance criteria of the SpiderFX® Embolic Protection Device are comparable to the predicate device and that the SpiderFX® Embolic Protection Device performs in a manner equivalent to the predicate device currently on the market for the same intended use.

9. Clinical Summary

DEFINITIVE Ca^{++} was a prospective, multi-center, non-randomized, single-arm study to compare the SilverHawk TurboHawk and the SpiderFX to performance goals derived from an observational multi-center registry (TALON) of subjects with lower extremity PAD who underwent revascularization with catheter-based plaque excision. The purpose of this study was to evaluate the safety and effectiveness of the SilverHawk/TurboHawk and the SpiderFX for the treatment of moderate to severely calcified peripheral arterial disease (PAD) in the superficial femoral and/or the popliteal arteries.

The primary safety endpoint of the DEFINITIVE Ca^{++} study was freedom from major adverse event (MAE) rate. MAE was defined as a serious adverse event that results in death, acute myocardial infarction, dissection (grade C or greater), clinical perforation, pseudo-aneurysm, thrombosis, distal embolism (clinically relevant), amputation, or clinically-driven TVR, through 30 days post-procedure, as adjudicated by the clinical events committee (CEC). The 30-day freedom from MAE rate was 93.1% (122/131). The 95% lower confidence limit was 88.3% (as calculated by the Exact method), greater than the performance goal of 85.5%. Therefore, the primary safety endpoint was met.

10. Conclusions

Based on the intended use, technological characteristics, safety and performance testing included in this submission, ev3 considers the proposed SpiderFX® Embolic Protection Device to be substantially equivalent to its predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

OCT 2 7 2011

ev3, Inc.
c/o Ms. Brenda Johnson
Principal Regulatory Affairs Specialist
3033 Campus Drive
Plymouth, MN 55441

Re: K111010
Trade/Device Name: SpiderFX Embolic Protection Device
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NTE
Dated: September 30, 2011
Received: October 3, 2011

Dear Ms. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. However, we remind you that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K111010

Device Name: SpiderFX® Embolic Protection Device

Indications for Use:

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K111010